REMARKS

This response, and accompanying request for continued examination, address the Final Office Action mailed on 03/15/02. Claims 1, 3-15, 48-51, and 54-65 are pending and new Claims 66-78 have been added.

Claims 1-10, 48-50 and 64-65 have been rejected under 35 U.S.C. §112, second paragraph. During the telephone conversation with the undersigned on August 6, 2002, the Examiner stated that she has also meant to reject Claims 51 and 56-58 under 35 U.S.C. §112, second paragraph. Claims 1, 48-51, 56-58, 64 and 65 have been amended to positively claim the combination. Withdrawal of the rejection with respect to Claims 1, 48-51, 56-58, 64 and 65 is respectfully requested. Claims 3-10 depend from Claim 1 and accordingly are also in allowable form.

Claims 1-5, and 50-55 have been rejected under 35 U.S.C. §102(b) as being anticipated by Khair et al. (U.S. Patent No. 5,425,710). Khair et al. simply teach a hollow cylindrical protector for a dilatation catheter balloon. With respect to Claim 1, Khair et al. fail to teach "a stent carrying a therapeutic substance" and "a sheath ... that prevents the therapeutic substance from ... absorbing" into the sheath, as recited by Claim 1. Accordingly, Claim 1 is patentably allowable over Khair et al. Claim 2 has been canceled. Claims 3-5 depend from Claim 1, and accordingly are patentably allowable over Khair et al. for at least the same reason.

With respect to Claim 50, Khair et al. fail to teach "a stent having a coating containing a medication; and a sheath for packaging the coated stent ... [for preventing] the medication from significantly diffusing out from the coating of the stent," as recited by Claim 50. Accordingly, Claim 50 is patentably allowable over Khair et al.

With respect to Claim 51, Khair et al. fail to teach "a stent" and "a sheath covering at least a portion of the stent, the sheath being made from a material that prevents the therapeutic substance from significantly absorbing into the sheath."

The Examiner's position is that the silicone layer described by Khair et al. has an inherent property of preventing the therapeutic material from being adsorbed into the protector. The Applicant respectfully disagrees. Those having ordinary skill in the art are aware that many kinds of silicones, for example, silicone elastomers, are very much permeable to gases or liquids. Khair et al. teach, for instance, that the "silicone is generally sticky." (Col. 5, Line 10). The stickiness is usually caused by low glass transition temperature of silicone macromolecule. It is well known in the art that low glass-transition temperature polymers generally represent poor barriers to diffusion of various substances through them, because at room temperature such polymers are in a visco-elastic state.

In fact, silicones' permeability is one of the properties which makes them valuable to be used in many applications, for example, for making "breathable" coatings, membranes, and the like. Therefore, contrary to the Examiner's interpretation, many silicones are not likely to prevent a therapeutic substance from being adsorbed by the protector, and at any rate, such prevention is not an "inherent property" of silicones.

Accordingly, Claim 51 is patentably allowable over Khair et al. Claims 52 and 53 have been canceled. Claims 54 and 55 depend from Claim 51, and are accordingly patentably allowable over Khair et al. for at least the same reason. Withdrawal of the rejection is respectfully requested.

Claims 1-4 and 50-54 have been rejected either under 35 U.S.C. §102(b) as being anticipated by Khair et al. or, alternatively, under 35 U.S.C. §103(a) as being obvious over

Khair et al. The Examiner asserted that the parylene coatings disclosed by Khair et al. either anticipate the material claimed in Claims 1-4 and 50-54 or make this material an obvious choice. The Applicant respectfully disagrees. With respect to the anticipation rejection, again Khair et al. fail to teach "a stent carrying a therapeutic substance," and "a sheath ... that prevents the therapeutic substance from ... absorbing" into the sheath, as recited by Claim 1. Khair et al. fail to teach "a stent having a coating containing a medication; and a sheath for packaging the coated stent ... [for preventing] the medication from significantly diffusing out from the coating of the stent," as recited by Claim 50. Khair et al. also fail to teach a sheath made from a material that during storage and transportation of a stent prevents the therapeutic substance carried by the stent from significantly absorbing into the sheath, as recited by Claim 51.

With respect to the obviousness rejection, Khair et al. teach that the parylene coating is needed to improve the lubriciousness (slipperiness) of the inner surface of the protector. Otherwise, using the silicone protector is difficult due to its stickiness (Col. 5, lines 9-23). Clearly, one having ordinary skill in the art reading Khair et al.'s disclosure on how to improve the slipperiness will not be motivated to modify a sheath to prevent absorption and/or diffusion of therapeutic agents from stents. Prevention of adsorption and/or diffusion of therapeutic agents from stents is vastly outside the purview of what is taught or suggested by Khair et al. Khair et al. are not even remotely concerned with the problem of maintaining levels of medication in stents at a therapeutically acceptable level until the stent is implanted in a patient.

Accordingly, Claims 1, 50 and 51 are each patentably allowable over Khair et al. Claim 2 has been canceled. Claims 3-4 depend from Claim 1, and accordingly are patentably allowable for at least the same reason. Claims 52 and 53 have been canceled. Claim 54 depends from Claim 51, and accordingly is patentably allowable for at least the same reason. Withdrawal of the rejection is respectfully requested.

Claims 1-5, 9, 10, 48-55, 59, and 60 have been rejected under 35 U.S.C. §103(a) as being obvious over Khair et al. and Marotta. The Examiner states that Khair et al. teach a sheath with a coating that has inherent properties of environmental barrier protection. Providing environmental protection and preventing adsorption and/or diffusion of a drug are different functions. Being able to provide one function does not automatically mean that the other function will be also provided. For instance, there are polymer coatings known in the art, which are quite permeable to liquids and/or gases yet provide very good environmental protection. Certain classes of silicone coatings is one example of such coatings. Contrariwise, there are many well known highly impermeable coatings which do not provide good environmental protection, for example, due to poor chemical resistivity.

Regardless, as indicated above, Claims 1 and 48-51 are patentably allowable over Khair et al. Marotta does not cure the deficiencies of Khair et al. Claims 3-5, 9 and 10 depend from Claim 1, and are patentably allowable for at least the same reason. Claims 54, 55, 59, and 60 depend from Claim 51, and are patentably allowable for at least the same reason. Withdrawal of the rejection is respectfully requested.

The Examiner stated that Claims 6-8, 56-58, 64 and 65 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, and to include all the limitations of the base claim and any intervening claims. Claims 6-8, 56-58, 64 and 65 have been rewritten in independent form and the rejections under 35 U.S.C. 112, second paragraph, have been overcome. It is submitted that Claims 6-8, 56-58, 64 and 65 are allowable.

CONCLUSION

Claims 1, 3-15, 48-51, and 54-78 are pending in this application. Examination and allowance of the claims is respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned at (415) 954-0349.

Date: August, 8,2002

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CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as express mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231, on August ___, 2002.

Date: _____ By:_____
Name of person signing certification

Version With Markings To Show Changes Made

In the Claims:

Please amend the claims as indicated below.

1. (Amended Twice) A [sheath for an implantable medical device, said implantable medical device] medical kit, comprising:

(a) a stent carrying a therapeutic substance which can be delivered to a subject; and

(b) [said] a sheath comprising a hollow body for removably covering at least a portion of [said implantable medical device] the stent, wherein [said] the body comprises a layer that prevents [said] the therapeutic substance from significantly absorbing into [said] the body or [said] the layer.

Please Cancel Claim 2 without prejudice.

3. (Amended) The [sheath] kit of Claim 1, wherein [said device is] the kit further includes a catheter and a balloon integrated with the catheter.

4. (Amended) The [sheath] kit of Claim 1, wherein [said] the layer is made from a polymeric material selected from a group consisting of polyolefins, polyurethanes, [cellulosics], derivatives of cellulose, polyesters, polyamides, poly(hexamethylene isophthalamide/terephthalamide), poly(ethylene terephthalate-co-p-oxybenzoate), poly(hydroxy amide ethers), polyacrylates, polyacrylonitrile, acrylonitrile/styrene copolymer, rubber-modified acrylonitrile/acrylate copolymer, poly(methyl methacrylate), liquid crystal polymers, poly(phenylene sulfide), polystyrenes, polycarbonates, poly(vinyl alcohols), poly(ethylene-vinyl alcohol), epoxies composed of bisphenol A based diepoxides with amine cure, aliphatic polyketones, polysulfones, poly(ester-sulfone), poly(urethane-sulfone), poly(carbonate-sulfone),

poly(3-hydroxyoxetane), poly(amino ethers), gelatin, amylose, parylene-C, parylene-D, parylene-N, and mixtures thereof.

5. (Amended) The [sheath] kit of Claim 4, wherein [said] the polyolefins are selected from a group consisting of polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride), poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), and mixtures thereof.

6. (Amended) [The sheath of Claim 4,] A medical kit, comprising:

(a) a stent carrying a therapeutic substance which can be delivered to a subject; and

(b) a sheath comprising a hollow body for removably covering at least a portion of the stent, wherein the body comprises a layer that prevents the therapeutic substance from significantly absorbing into the body or the layer, wherein the layer is made from a polyurethane having [said polyurethane has] a glass transition temperature above a storage temperature.

7. (Amended) [The sheath of Claim 4,] A medical kit, comprising:

(a) a stent carrying a therapeutic substance which can be delivered to a subject; and

(b) a sheath comprising a hollow body for removably covering at least a portion of the stent, wherein the body comprises a layer that prevents the therapeutic substance from significantly absorbing into the body or the layer, wherein the layer is made from a polyurethane having [said polyurethane has]a non-polar soft segment, [said] the non-polar soft segment is selected from the group consisting of hydrocarbons, silicones, fluorosilicones, and mixtures thereof.

8. (Amended Twice) [The sheath of Claim 4,] A medical kit, comprising:

(a) a stent carrying a therapeutic substance which can be delivered to a subject; and

(b) a sheath comprising a hollow body for removably covering at least a portion of the stent, wherein the body comprises a layer that prevents the therapeutic substance from significantly absorbing into the body or the layer, wherein the layer is made from derivatives of cellulose [said cellulosics are] selected from the group consisting of cellulose acetate having a degree of substitution greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, and mixtures thereof.

equivalent films

9. (Amended) The [sheath] kit of Claim 4, wherein [said] the polyesters are selected from a group consisting of poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), and mixtures thereof.

10. (Amended) The [sheath] kit of Claim 4, wherein [said] the polyamides are selected from a group consisting of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof.

11. (Amended Twice) The [sheath] kit of Claim 1, wherein [said] the layer is made from a polymeric material and fillers added to [said] the polymeric material.

12. (Amended) The [sheath] kit of Claim 1, wherein the layer is made from glass.

13. (Amended) The [sheath] kit of Claim 1, wherein [said] the layer is made from a metallic material.

14. (Amended Twice) The [sheath] kit of Claim 1, wherein [said] the layer comprises a therapeutic substance contacting surface having a metallic substance disposed on [said] the therapeutic substance contacting surface.

15. (Amended Twice) The [sheath] kit of Claim 1, wherein [said] the layer comprises a therapeutic substance contacting surface, [said] the therapeutic substance contacting surface

having a coating of a main group element oxide formed thereon, [said] the main group element oxide coating is selected from a group of silicon oxide and metal oxide.

48. (Amended) A medical kit, comprising:

(a) a medicated stent; and

(b) a sheath for packaging [a] the medicated stent during transportation or storage of the medicated stent, the sheath comprising a hollow, tubular body in which the medicated stent [can be inserted] is housed during transportation or storage of the medicated stent, the sheath being made from a material [or an inner surface of the sheath being covered with a material which has] having an oxygen transmission rate of not more than about 200 cc/100 in^2, for 1 mil per 24 hours at 73° F, 75% relative humidity, and 1 atmosphere.

49. (Amended) A medical kit, comprising:

(a) a medicated stent; and

(b) a sheath for packaging [a] the medicated stent during transportation or storage of the medicated stent, the sheath comprising a hollow, tubular body in which the medicated stent [can be inserted] is housed during transportation or storage of the medicated stent, the sheath being made from a material [or an inner surface of the sheath being covered with a material which has] having a water vapor transmission rate of not more than 20 gm/100 in^2, for 1 mil per 24 hours at 100° F, 90% relative humidity, and 1 atmosphere.

50. (Amended) A [sheath for packaging a stent,] medical kit, comprising:

(a) a [the] stent having a coating containing a medication[,]; and

(b) a sheath for packaging the coated stent, the sheath comprising a hollow tubular body in which the stent can be removably inserted, wherein the body is made from a material [or

is lined with a material] that prevents the medication from significantly diffusing out from the coating of the stent.

51. (Amended) A [sheath for covering an implantable medical device,] medical kit, comprising:

(a) a stent [said implantable medical device] carrying a therapeutic substance which can be delivered to a subject[,]; and

(b) [said] a sheath for covering at least a portion of the stent, the sheath being made from a material that prevents [said] the therapeutic substance from significantly absorbing into [said] the sheath.

Please cancel Claims 52 and 53.

54. (Amended) The [sheath] kit of Claim 51, wherein [said] the material is selected from a group consisting of polyolefins, polyurethanes, [cellulosics] derivatives of cellulose, polyesters, polyamides, poly(hexamethylene isophthalamide/terephthalamide), poly(ethylene terephthalate-co-p-oxybenzoate), poly(hydroxyamide ethers), polyacrylates, polyacrylonitrile, acrylonitrile/styrene copolymer, rubber-modified acrylonitrile/acrylate copolymer, poly(methyl methacrylate), liquid crystal polymers, poly(phenylene sulfide), polystyrenes, polycarbonates, poly(vinyl alcohols), poly(ethylene-vinyl alcohol), epoxies composed of bisphenol A based diepoxides with amine cure, aliphatic polyketones, polysulfones, poly(ester-sulfone), poly(urethane-sulfone), poly(carbonate-sulfone), poly(3-hydroxyoxetane), poly(amino ethers), gelatin, amylose, parylene-C, parylene-D, parylene-N, and mixture thereof.

55. (Amended) The [sheath] kit of Claim 54, wherein [said] the polyolefins are selected from a group consisting of polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride), poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), and mixtures thereof.

56. (Amended) [The sheath of Claim 54,] A medical kit, comprising:

(a) an implantable medical device carrying a therapeutic substance which can be delivered to a subject; and

(b) a sheath made from a material that prevents the therapeutic substance from significantly absorbing into the sheath, wherein the material is a polyurethane [said polyurethane has] having a glass transition temperature above a storage temperature.

57. (Amended) [The sheath of Claim 54,] A medical kit, comprising:

(a) an implantable medical device carrying a therapeutic substance which can be delivered to a subject; and

(b) a sheath made from a material that prevents the therapeutic substance from significantly absorbing into the sheath, wherein the material is a polyurethane [said polyurethane has] having a non-polar soft segment, [said] the non-polar soft segment is selected from the group consisting of hydrocarbons, silicones, fluorosilicones, and mixtures thereof.

58. (Amended) [The sheath of Claim 54,] A medical kit, comprising:

(a) an implantable medical device carrying a therapeutic substance which can be delivered to a subject; and

(b) a sheath made from a material that prevents the therapeutic substance from significantly absorbing into the sheath, wherein the material is made from derivatives of cellulose [said cellulosics are] selected from the group consisting of cellulose acetate having a degree of substitution greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, and mixtures thereof.

59. (Amended) The [sheath] kit of Claim 54, wherein [said] the polyesters are selected from a group consisting of poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), and mixtures thereof.

60. (Amended) The [sheath] kit of Claim 54, wherein [said] the polyamides are selected from a group consisting of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof.

61. (Amended) The [sheath] kit of Claim 51, wherein [said] the material is a polymeric material having fillers added thereto.

62. (Amended) The [sheath] kit of Claim 51, wherein [said] the material comprises glass.

63. (Amended) The [sheath] kit of Claim 51, wherein [said] the material comprises a metallic material.

64. (Amended) [The sheath of Claim 1,] A medical kit, comprising:

(a) a stent carrying a therapeutic substance which can be delivered to a subject; and

(b) a sheath comprising a hollow body for removably covering at least a portion of the stent, wherein the body comprises a layer that prevents the therapeutic substance from significantly absorbing into the body or the layer, wherein [said] the layer is a sulfonated or a fluorinated polymeric layer.

65. (Amended) [The sheath of Claim 1,] A medical kit, comprising:

(a) a stent carrying a therapeutic substance which can be delivered to a subject; and

(b) a sheath comprising a hollow body for removably covering at least a portion of the stent, wherein the body comprises a layer that prevents the therapeutic substance from significantly absorbing into the body or the layer, wherein [said] the layer is made from a carbide or nitride compound.

Please add the following claims:

-- 66. A medical kit, comprising:

(a) a medicated stent; and

(b) a sheath for packaging the medicated stent during transportation or storage of the medicated stent, the sheath comprising a hollow, tubular body in which the medicated stent is contained during transportation or storage of the medicated stent, an inner surface of the sheath being covered with a material having an oxygen transmission rate of not more than about 200 cc/100 in^2, for 1 mil per 24 hours at 73° F, 75% relative humidity, and 1 atmosphere.

67. A medical kit, comprising:

(a) a medicated stent; and

(b) a sheath for packaging the medicated stent during transportation or storage of the medicated stent, the sheath comprising a hollow, tubular body in which the medicated stent is contained during transportation or storage of the medicated stent, an inner surface of the sheath being covered with a material having a water vapor transmission rate of not more than 20 gm/100 in^2, for 1 mil per 24 hours at 100° F, 90% relative humidity, and 1 atmosphere.

68. A medical kit, comprising:

(a) a stent having a coating containing a therapeutic substance; and

(b) a sheath for packaging the stent, the sheath comprising a hollow tubular body in which the stent can be removably inserted, wherein the body is lined with a material that prevents the medication from significantly diffusing out from the coating of the stent.

69. A sheath for covering an implantable medical device, the implantable medical device carrying a therapeutic substance which can be delivered to a subject, the sheath comprising a hollow body made of a material that prevents the therapeutic substance from significantly absorbing into the body, wherein the material comprises a sulfonated or a fluorinated polymer.

70. A sheath for covering an implantable medical device, the implantable medical device carrying a therapeutic substance which can be delivered to a subject, the sheath comprising a hollow body made of a material that prevents the therapeutic substance from significantly absorbing into the body, wherein the material comprises a carbide or nitride compound.

71. A sheath for covering an implantable medical device, the implantable medical device carrying a therapeutic substance which can be delivered to a subject, the sheath comprising a hollow body made of a material that prevents the therapeutic substance from significantly diffusing out from the medical device, wherein the material is selected from a group consisting of:

(a) polyurethane having a glass transition temperature above a storage temperature;

(b) polyurethane having a non-polar soft segment, the non-polar soft segment is selected from the group consisting of hydrocarbons, silicones, fluorosilicones, and mixtures thereof;

(c) a derivative of cellulose selected from the group consisting of cellulose acetate having a degree of substitution greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, and mixtures thereof;

(d) sulfonated polymers;

(e) fluorinated polymers;

(f) carbide compounds;

(g) nitride compounds;

(h) a polyolefin selected from a group consisting of polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride), poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), and mixtures thereof;

(i) a polyester selected from a group consisting of poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), and mixtures thereof;

(j) a polyamide selected from a group consisting of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof; and

(k) mixtures thereof.

72. A sheath for covering an implantable medical device, the implantable medical device carrying a therapeutic substance which can be delivered to a subject, the sheath comprising a hollow body comprising a layer that prevents the therapeutic substance from significantly diffusing out from the medical device, wherein the layer is made from a material selected from a group consisting of:

(a) polyurethane having a glass transition temperature above a storage temperature;

(b) polyurethane having a non-polar soft segment, the non-polar soft segment is selected from the group consisting of hydrocarbons, silicones, fluorosilicones, and mixtures thereof;

(c) a derivative of cellulose selected from the group consisting of cellulose acetate having a degree of substitution greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, and mixtures thereof;

(d) sulfonated polymers;

(e) fluorinated polymers;

(f) carbide compounds;

(g) nitride compounds;

(h) a polyolefin selected from a group consisting of polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride), poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), and mixtures thereof;

(i) a polyester selected from a group consisting of poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), and mixtures thereof;

(j) a polyamide selected from a group consisting of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof; and

(k) mixtures thereof.

73. A sheath for covering an implantable medical device, the implantable medical device carrying a therapeutic substance which can be delivered to a subject, the sheath comprising a hollow body made of a material that prevents the therapeutic substance from significantly absorbing into the body, wherein the material comprises a polyolefin, wherein the polyolefin is selected from a group consisting of polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride), poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), and mixtures thereof.

74. A sheath for covering an implantable medical device, the implantable medical device carrying a therapeutic substance which can be delivered to a subject, the sheath comprising a hollow body comprising a layer that prevents the therapeutic substance from significantly absorbing into the layer, wherein the layer is made from a material comprising a polyolefin, wherein the polyolefin is selected from a group consisting of polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride), poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), and mixtures thereof.

75. A sheath for covering an implantable medical device, the implantable medical device carrying a therapeutic substance which can be delivered to a subject, the sheath comprising a hollow body made of a material that prevents the therapeutic substance from significantly absorbing into the body, wherein the material comprises a polyester, wherein the

polyester is selected from a group consisting of poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), and mixtures thereof.

76. A sheath for covering an implantable medical device, the implantable medical device carrying a therapeutic substance which can be delivered to a subject, the sheath comprising a hollow body comprising a layer that prevents the therapeutic substance from significantly absorbing into the layer, wherein the layer is made from a material comprising a polyester, wherein the polyester is selected from a group consisting of poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), and mixtures thereof.

77. A sheath for covering an implantable medical device, the implantable medical device carrying a therapeutic substance which can be delivered to a subject, the sheath comprising a hollow body made of a material that prevents the therapeutic substance from significantly absorbing into the body, wherein the material comprises a polyamide, wherein the polyamide is selected from a group consisting of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof.

78. A sheath for covering an implantable medical device, the implantable medical device carrying a therapeutic substance which can be delivered to a subject, the sheath comprising a hollow body comprising a layer that prevents the therapeutic substance from significantly absorbing into the layer, wherein the layer is made from a material comprising a polyamide, wherein the polyamide is selected from a group consisting of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof.--